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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/988,115	11/16/2001	James M. Robl	50195/008003	8075

21559 7590 09/11/2003

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SEP 15 2003

CLARK &amp; ELBING LLP

EXAMINER

CROUCH, DEBORAH

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 09/11/2003

*10/10/03*  
*3/11/04*

Please find below and/or attached an Office communication concerning this application or proceeding.

*sem*

ACTION DUE *Reply*  
DUE DATE *12.11.03*  
ESP *3.11.04*  
INITIALS *mh*

**Office Action Summary**

Application N .

09/988,115

Applicant(s)

ROBL ET AL.

Examiner

Deborah Crouch, Ph.D.

Art Unit

1632

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-48 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner. \_\_\_\_\_
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) ☐ All b) ☐ Some \* c) ☐ None of:  
 1. ☐ Certified copies of the priority documents have been received.  
 2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

Application/Control Number: 09/988,115

Page 2

Art Unit: 1632

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-19 and 21-29, drawn to a transgenic ungulate or an ungulate somatic cell comprising one or more nucleic acids encoding a xenogenous immunoglobulin gene which undergoes rearrangement, an ungulate somatic cell and a transgenic ungulate, classified in class 800, subclasses 6, 15, 16 or 17.
- II. Claim 20, drawn to a hybridoma, classified in class 435, subclass 326.
- III. Claims 30-38, drawn to a method of producing a transgenic ungulate by transfer of a cell, or its chromatin mass or its nucleus into an oocyte, wherein the cell comprises an mutation in an endogenous antibody heavy chain or light chain nucleic acid, classified in class 800, subclass 24.
- IV. Claim 42, drawn to a method of producing a transgenic ungulate comprising inserting into an oocyte a cell, its chromatin mass or its nucleus, where the cell comprise a mutation in an endogenous antibody gene, classified in class 800, subclass 24.
- V. Claim 43, drawn to a method of producing a transgenic ungulate comprising inserting into an oocyte a cell, its chromatin mass or its nucleus, where the cell comprise a mutation in an endogenous  $\alpha$ -1,3-galactosyltransferase gene, classified in class 800, subclass 24.
- VI. Claims 44, drawn to a method of producing a transgenic ungulate comprising inserting into an oocyte a cell, its chromatin mass or its nucleus, where the cell comprise a mutation in an endogenous prion gene, classified in class 800, subclass 24.
- VII. Claims 45 and 46, drawn to a method of producing a transgenic ungulate comprising inserting into an oocyte a cell, its chromatin mass or its nucleus,

Application/Control Number: 09/988,115  
Art Unit: 1632

Page 3

where the cell comprise a mutation in an endogenous J gene or a nucleic acid encoding a J gene, classified in class 800, subclass 24.

VIII. Claims 47, drawn to ungulate serum comprising human polyclonal immunoglobulins, classified in class 424, subclass 130.1.

IX. Claim 48, drawn to ungulate milk comprising human polyclonal immunoglobulins, classified in class 426, subclass 580.

Claims 39-41 link(s) inventions V-VII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 39-41. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because:

Inventions I and II are distinct because they are of separate uses. The ungulate of invention I can be used to produce polyclonal antibodies. The hybridoma of invention II can be used to produce monoclonal antibodies.

Inventions I and III-VII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the

Application/Control Number: 09/988,115  
Art Unit: 1632

Page 4

product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the ungulate can be made by transgenic methods where the gene is injected into a fertilized oocyte.

Inventions I and VIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the serum of group VIII can be made by adding human immunoglobulins to ungulate serum.

Inventions I and IX are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the milk of group IX can be made by adding human immunoglobulins to ungulate milk.

Inventions II and each of inventions III-IX are mutually exclusive and independent. The hybridoma is not required for the implementation of any of the inventions III-IX, and vice versa.

Inventions III-VII are each mutually exclusive and independent inventions. Each of the inventions require materially different protocols as to the donor cell type, whether or not there is a mutated endogenous gene, whether or not there are xenogenous DNA sequences and the particular gene or xenogenous DNA sequences can either encode an antibody,  $\alpha$ -1,3-galactosyltransferase, prion or a J chain. These various methods are not required for the implementation of any of the other methods.

Application/Control Number: 09/988,115  
Art Unit: 1632

Page 5

Inventions III-VII and inventions VIII and IX are mutually exclusive and independent. The methods of producing a transgenic ungulate of invention III-VII are not required to produce either the ungulate serum of invention VIII or ungulate milk of invention IX, and vice versa.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and because of their recognized-divergent subject-matter, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Groups I, II, VIII and IX is not co-extensive with each other or the search required for Groups III-VII, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Application/Control Number: 09/988,115  
Art Unit: 1632

Page 6

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 703-308-1126. The examiner can normally be reached on M-Th, 8:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Deborah Crouch, Ph.D.  
Primary Examiner  
Art Unit 1632

dc  
September 10, 2003

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